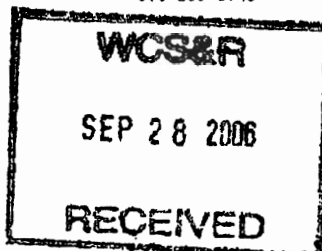


EXHIBIT 13

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 Los Angeles Superior Court

SEP 28 2006

John A. Clark, Executive Officer/Clerk
 By [Signature] Deputy

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6 **SUPERIOR COURT OF THE STATE OF CALIFORNIA**7 **FOR THE COUNTY OF LOS ANGELES**

8 ANNE E. CLAYTON;

9 Plaintiff,

10 vs.

11 MERCK & CO., INC., a New Jersey
 corporation; MCKESSON
 12 CORPORATION, a Delaware corporation;
 DOES 1-50,

13 Defendants.

Case No: BC359113**COMPLAINT FOR DAMAGES**

and

DEMAND FOR JURY TRIAL

14 For their Complaint against the defendants, plaintiff allege:

15 **PARTIES**

16 1. Plaintiff Anne E. Clayton, is a citizen of the State of Idaho, and Plaintiff Anne E.
 17 Clayton was prescribed and ingested Fosamax™.

18 2. Defendant Merck & Co., Inc., (hereafter, "Merck") is a corporation organized
 19 and existing under the laws of the State of New Jersey, with its principal place of business
 20 in New Jersey. Merck was and is authorized to do business in the State of California and was
 21 engaged in substantial commerce and business activity in the County of Los Angeles.

22 3. Defendant McKesson Corporation (hereafter, "McKesson") was and is a
 23 corporation organized and existing under the laws of the State of Delaware, with its principal
 24 place of business in San Francisco, California. McKesson was and is authorized to do
 25 business in the State of California and was engaged in substantial commerce and business
 26

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1 activity in the County of Los Angeles.

2 4. The true names or capacities, whether individual, corporate, or otherwise, of
3 Defendants Doe 1-50, are unknown to Plaintiff who therefore sue said Defendants by such
4 fictitious names. Plaintiff believe and allege that each of the Defendants designated herein
5 by fictitious names is in some manner legally responsible for the events and happenings
6 herein referred to and proximately caused foreseeable damages to Plaintiff as alleged herein.

7 5. At all times herein mentioned, "Defendants" include all named Defendants
8 herein as well as Defendants Does 1-50.

9 6. At all relevant times Defendants, through their agents, servants, employees and
10 apparent agents, were the designers, manufacturers, marketers, distributors and/or sellers of
11 Fosamax™, a bisphosphonate drug used primarily to mitigate or reverse the effects of
12 osteoporosis, osteopenia, and Paget's Disease.

13 7. Defendants, either directly or through their agents, apparent agents, servants
14 or employees, at all relevant times, sold and distributed Fosamax™ in the State of California.

15 8. Defendants derive substantial revenue from pharmaceutical products used or
16 consumed in the State of California.

17 9. Defendants expected or should have expected, that their business activities
18 could or would have consequences within the State of California.

19 10. Plaintiff bring this action to recover damages, restitution, refunds, loss of
20 consortium and/or for equitable, injunctive and declaratory relief against Defendants.

21 11. Defendants placed Fosamax™ into the stream of worldwide commerce and
22 interstate commerce in the United States. It did so without adequate testing and with no
23 warning that the drug carried with it a risk of causing osteonecrosis of the jaw.

24 12. Plaintiff needs continued medical monitoring to prevent or mitigate the future
25 onset of osteonecrosis of the jaw or treat osteonecrosis of the jaw which has already
26 manifested.

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1 Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's
2 Disease. Other drugs within this class, such as Aredia™ and Zometa™, are used as
3 chemotherapy and as adjunct chemotherapy, but are not indicated for use in non-cancerous
4 conditions such as osteoporosis.

5 21. There are two classes of bisphosphonates: the N-containing (nitrogenous) and
6 the non-N-containing (non nitrogenous) bisphosphonates. The nitrogenous bisphosphonates
7 include the following: pamidronate (Aredia™), ibandronate (Bondronat), and alendronate
8 (Fosamax™). The non-nitrogenous bisphosphonates include the following: etridonate
9 (Didronel™), clodronate (Bonefos™ and Loron™), and tiludronate (Skelid™). Alendronate
10 contains a nitrogen atom. The Physicians Desk Reference ("PDR") for Fosamax™ confirms
11 that the molecule contains a nitrogen atom.

12 22. Throughout the 1990's and 2000's, medical articles and studies appeared
13 reporting the frequent and common occurrence of osteonecrosis of the jaw within
14 chemotherapy patients taking nitrogenous bisphosphonates. As with its reported and
15 acknowledged side effects concerning irritation, erosion, and inflammation of the upper
16 gastrointestinal tract, Defendants knew or should have known that Fosamax™, as a
17 nitrogenous bisphosphonate, shared an adverse event profile similar to the other drugs within
18 this specific subclass of bisphosphonates (i.e., those containing nitrogen).

19 23. Defendants knew and or should have known that bisphosphonates, including
20 Fosamax™, inhibit endothelial cell function. Similarly, Defendants knew or should have
21 known that bisphosphonates also inhibit vascularization of the affected area and induce
22 ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and
23 that these ischemic changes appear to be cumulative in nature, all of which provided
24 Defendants with more than reasonable evidence of a causal association between the use of
25 Fosamax™ and osteonecrosis, a clinically significant hazard.

26 24. Defendants also knew or should have known that these factors combine to

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1 create a compromised vascular supply in the affected area. As a result, a minor injury or
2 disease can turn into a non-healing wound, which can progress to widespread osteomyelitis
3 (inflammation of bone marrow) and ultimately osteonecrosis (bone death).

4 25. Dentists are now being advised by dental associations to refrain from
5 undertaking any invasive procedure (such as drilling a cavity) for any patient on Fosamax™.

6 26. Once the osteonecrosis begins and becomes symptomatic, it is very difficult
7 to treat and typically is not reversible.

8 27. Shortly after Defendants began selling Fosamax™, reports of osteonecrosis
9 of the jaw and other dental complications among users began surfacing, indicating that
10 Fosamax™ shared the class effects of the other nitrogenous bisphosphonates. Despite this
11 knowledge, Defendants failed to implement further studies regarding the risk of
12 osteonecrosis of the jaw relative to Fosamax™. Rather than evaluating and verifying the
13 safety of Fosamax™ with respect to osteonecrosis of the jaw, Defendants proposed further
14 uses of Fosamax™, such as Fosamax™-D, and sought to extend the exclusivity period of
15 Fosamax™ through 2018.

16 28. Osteonecrosis of the jaw is a serious medical event and can result in severe
17 disability and death.

18 29. Since Fosamax™ was released, the FDA has received a significant number of
19 reports of osteonecrosis of the jaw among users of Fosamax™.

20 30. On August 25, 2004 the United States Food & Drug Administration ("FDA")
21 posted its ODS Postmarketing Safety Review on bisphosphonates, specifically pamidronate
22 (Aredia™), zoledronic acid (Zometa™), risedronate (Actonel™), and alendronate
23 (Fosamax™). This was an epidemiologic review of the FDA adverse events database
24 conducted by the FDA's Division of Drug Risk Evaluation.

25 31. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis
26 of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review

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1 indicated that the osteonecrosis of the jaw was a class effect which specifically extended to
2 the oral bisphosphonate, Fosamax™.

3 32. As a result, the FDA recommended and stated that the labeling for Fosamax™
4 should be amended by Merck to specifically warn about the risk of osteonecrosis of the jaw.
5 Defendants have refused to accede to the FDA's request and, to this day, still do not
6 adequately warn of the risk of osteonecrosis of the jaw in its Fosamax™ labeling.

7 33. Rather than warn patients and despite knowledge known by Defendants about
8 increased risk of osteonecrosis of the jaw on patients using Fosamax™, Defendants continue
9 to defend Fosamax™, mislead physicians and the public, and minimize unfavorable findings.

10
11 34. Fosamax™ is one of the Defendants' top selling drugs, averaging more than
12 \$3 billion a year in sales.

13 35. Consumers, including Plaintiff, who have used Fosamax™ for treatment of
14 osteoporosis, have several alternative safer products available to treat the conditions.

15 36. Defendants knew of the significant risk of dental and oral complications caused
16 by ingestion of Fosamax™, but Defendants did not adequately and sufficiently warn
17 consumers, including Plaintiff, or the medical community, of such risk.

18 37. As a direct result, Plaintiff was prescribed Fosamax™ and has been
19 permanently and severely injured, having suffered serious consequences from the ingestion
20 of Fosamax™. Plaintiff requires and will in the future require ongoing medical care and
21 treatment.

22 38. Plaintiff has suffered mental anguish from the knowledge that Plaintiff will
23 have life-long complications as a result of the injuries Plaintiff sustained from the use of
24 Fosamax™.

25 39. Plaintiff was prescribed and used Fosamax™ in a foreseeable manner pursuant
26 to her prescriptions.

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1 40. Plaintiff, as a direct and proximate result of using Fosamax™, suffered severe
2 mental and physical pain and suffering and has sustained permanent injuries and emotional
3 distress.

4 41. Plaintiff used Fosamax™ which had been provided in a condition that was
5 substantially the same as the condition in which it was manufactured and sold.

6 42. Plaintiff would not have used Fosamax™ had Defendants properly disclosed
7 the risks associated with the drug. Alternatively, Plaintiff would have known and/or
8 recognized the precursor events of osteonecrosis of the jaw and would have been able to
9 avoid the clinical manifestation of the disease.

10 43. Defendant, through their affirmative misrepresentations and omissions, actively
11 concealed from Plaintiff and their physicians the true and significant risks associated with
12 taking Fosamax™. The running of any applicable Statute of Limitations has been tolled by
13 reason of Defendants' fraudulent concealment.

14 44. As a result of Defendants' actions, Plaintiff and her prescribing physicians
15 were unaware, and could not have reasonably known or have learned through reasonable
16 diligence, that Plaintiff had been exposed to the risk identified in this complaint, and that
17 those risks were the direct and proximate result of Defendants' acts, omissions, and
18 misrepresentations.

19 **FIRST CAUSE OF ACTION**
20 **(Negligence)**

21 45. Plaintiff restates the allegations set forth above as if fully rewritten herein.

22 46. Defendants owed Plaintiff, and other consumers, a duty to exercise reasonable
23 care when designing, manufacturing, marketing, advertising, distributing, and selling
24 Fosamax™.

25 47. Defendants failed to exercise due care under the circumstances and therefore
26 breached this duty by:

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- 1 a. Failing to properly and thoroughly test Fosamax™ before releasing the
- 2 drug to market;
- 3 b. Failing to properly and thoroughly analyze the data resulting from the
- 4 pre-marketing tests of Fosamax™;
- 5 c. Failing to conduct sufficient post-market testing and surveillance of
- 6 Fosamax™;
- 7 d. Designing, manufacturing, marketing, advertising, distributing, and
- 8 selling Fosamax™ to consumers, including Plaintiff, without an adequate warning of the
- 9 significant and dangerous risks of Fosamax™ and without proper instructions to avoid the
- 10 harm which could foreseeably occur as a result of using the drug;
- 11 e. Failing to exercise due care when advertising and promoting
- 12 Fosamax™; and,
- 13 f. Negligently continuing to manufacture, market, advertise, and distribute
- 14 Fosamax™ after Defendants knew or should have known of its adverse effects.

15 48. As a direct and proximate consequence of Defendants' actions, omissions, and
16 misrepresentations, Plaintiff suffered serious personal injuries. In addition, Plaintiff required
17 and will continue to require healthcare and services. Plaintiff has incurred and will continue
18 to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer
19 diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of
20 premature death, aggravation of preexisting conditions and activation of latent conditions,
21 and other losses and damages. Plaintiff's direct medical losses and costs include care for
22 hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff
23 has incurred and will continue to incur mental and physical pain and suffering. Plaintiff has
24 suffered loss of wages and wage-earning capacity.

25 49. Defendants' conduct as described above was committed with knowing,
26 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights

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1 and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so
2 as to punish Defendants and deter them from similar conduct in the future.

3 WHEREFORE, Plaintiff demands judgment against Defendants and seek
4 compensatory damages, and exemplary and punitive damages together with interest, the costs of suit,
5 attorneys' fees and such other and future relief as the Court deems just and proper.

6 **SECOND CAUSE OF ACTION**
7 **(Strict Liability)**

8 50. Plaintiff restates the allegations set forth above as if fully rewritten herein.

9 51. Defendants manufactured, sold, distributed, marketed, and/or supplied
10 Fosamax™ in a defective and unreasonably dangerous condition to consumer, including
11 Plaintiff.

12 52. Defendants designed, manufactured, sold, distributed, supplied marketed,
13 and/or promoted Fosamax™, which was expected to reach and did in fact reach consumers,
14 including Plaintiff, without substantial change in the condition in which it was manufactured
15 and sold by Defendants.

16 53. Plaintiff used Fosamax™ as prescribed and in a manner normally intended,
17 recommended, promoted and marketed by Defendants.

18 54. Fosamax™ failed to perform safely when used by ordinary consumers,
19 including Plaintiff, including when it was used as intended and in a reasonably foreseeable
20 manner.

21 55. Fosamax™ was defective in its design and was unreasonably dangerous in that
22 its unforeseeable risks exceeded the benefits associated with its design or formulation.

23 56. Fosamax™ was defective in design or formulation in that it posed a greater
24 likelihood of injury than other similar medications and was more dangerous than an ordinary
25 consumer could reasonably foresee or anticipate.

26 57. Fosamax™ was defective in its design and was unreasonably dangerous in that

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1 it neither bore nor was packaged with nor accompanied by warnings adequate to alert
2 consumers, including Plaintiff, of the risks described herein, including, but not limited to, the
3 risk of osteonecrosis of the jaw.

4 58. Although Defendants knew or should have known of the defective nature of
5 Fosamax™, it continued to design, manufacture, market, and sell Fosamax™ so as to
6 maximize sales and profits at the expense of the public health and safety. By so acting,
7 Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by
8 Fosamax™.

9 59. Plaintiff could not, through the exercise of reasonable care, have discovered
10 Fosamax™'s defects or perceived the dangers posed by the drug.

11 60. As a direct and proximate consequence of Defendants' conduct, Plaintiff
12 suffered serious personal injuries. In addition, Plaintiff required and will continue to require
13 healthcare. Plaintiff has incurred and will continue to incur medical and related expenses,
14 Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment
15 of life, a diminished quality of life, increased risk of premature death, aggravation of
16 preexisting conditions and activation of latent conditions, and other losses and damages.
17 Plaintiff's direct medical losses and costs include care for hospitalization, physician care,
18 monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue
19 to incur mental and physical pain and suffering. Plaintiff has suffered loss of wages and
20 wage-earning capacity.

21 61. Defendants' conduct as described above was committed with knowing,
22 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights
23 and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so
24 as to punish Defendants and deter them from similar conduct in the future.

25 WHEREFORE, Plaintiff demands judgment against Defendants and seeks
26 compensatory damages, and exemplary and punitive damages together with interest, the costs of suit,

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1 attorneys' fees and such other and future relief as the Court deems just and proper.

2 / / /

3 **THIRD CAUSE OF ACTION**
4 **(Breach of Express Warranty)**

5 62. Plaintiff restate the allegations set forth above as if fully rewritten herein.

6 63. Defendants expressly represented to Plaintiff and other consumers and the
7 medical community that Fosamax™ was safe and fit for its intended purposes, that it was of
8 merchantable quality, that it did not produce any dangerous side effects, and that it was
9 adequately tested.

10 64. Fosamax™ does not conform to Defendants' express representations because
11 it is not safe, has numerous and serious side effects, and causes severe and permanent
12 injuries.

13 65. At all relevant times Fosamax™ did not perform as safely as an ordinary
14 consumer would expect, when used as intended or in a reasonably foreseeable manner.

15 66. Plaintiff, other consumers, and the medical community relied upon Defendants'
16 express warranties.

17 67. As a direct and proximate result of Defendants' actions, Plaintiff suffered
18 serious personal injuries. In addition, Plaintiff required and will continue to require
19 healthcare and services. Plaintiff has incurred and will continue to incur medical and related
20 expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the
21 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation
22 of preexisting conditions and activation of latent conditions, and other losses and damages.
23 Plaintiff' direct medical losses and costs include care for hospitalization, physician care,
24 monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue
25 to incur mental and physical pain and suffering. Plaintiff has suffered loss of wages and
26 wage-earning capacity.

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1 68. Defendants' conduct as described above was committed with knowing,
2 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights
3 and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so
4 as to punish Defendants and deter them from similar conduct in the future.

5 WHEREFORE, Plaintiff demands judgment against Defendants and seek
6 compensatory damages, and exemplary and punitive damages together with interest, the costs of suit,
7 attorneys' fees and such other and future relief as the Court deems just and proper.

8 **FOURTH CAUSE OF ACTION**
9 **(Breach of Implied Warranty)**

10 69. Plaintiff restates the allegations set forth above as if fully rewritten herein.

11 70. Defendants manufactured, distributed, advertised, promoted and sold
12 Fosamax™.

13 71. At all relevant times, Defendants knew of the use for which Fosamax™ was
14 intended and impliedly warranted the product to be of merchantable quality and safe and fit
15 for such use.

16 72. Defendants were aware that consumers, including Plaintiff, would use
17 Fosamax™ for treatment of osteoporosis and for other purposes.

18 73. Plaintiff and the medical community reasonably relied upon the judgment and
19 sensibility of Defendants to sell Fosamax™ only if it was indeed of merchantable quality and
20 safe and fit for its intended use.

21 74. Defendants breached their implied warranty to consumers, including Plaintiff;
22 Fosamax™ was not of merchantable quality or safe and fit for its intended use.

23 75. Consumers, including Plaintiff, and the medical community, reasonably relied
24 upon Defendants' implied warranty for Fosamax™.

25 76. Fosamax™ reached consumers without substantial change in the condition in
26 which it was manufactured and sold by Defendants.

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1 77. As a direct and proximate result of Defendants' actions, Plaintiff suffered
2 serious personal injuries. In addition, Plaintiff required and will continue to require
3 healthcare services. Plaintiff has incurred and will continue to incur medical and related
4 expenses. Plaintiff has suffered and will continue to suffer diminished capacity for
5 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation
6 of preexisting conditions and activation of latent conditions, and other losses and damages.
7 Plaintiff's direct medical losses and cost include care for hospitalization, physician care,
8 monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to
9 incur mental and physical pain and suffering. Plaintiff have suffered loss of wages and
10 wage-earning capacity.

11 78. Defendants' conduct as described above was committed with knowing,
12 conscious, wanton, willful, and deliberate disregard for the value of human life and rights
13 and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so
14 as to punish Defendant and deter it from similar conduct in the future.

15 WHEREFORE, Plaintiff demands judgment against Defendants and seek
16 compensatory damages, and exemplary and punitive damages together with interest, the costs of suit,
17 attorneys' fees and such other and future relief as the Court deems just and proper.

18 **FIFTH CAUSE OF ACTION**
19 **(Fraudulent Misrepresentation)**

20 79. Plaintiff restate the allegations set forth above as if fully rewritten herein.

21 80. Defendants made fraudulent misrepresentations with respect to Fosamax™ in
22 the following particulars:

23 a. Defendants represented through their labeling, advertising, marketing
24 materials, detail persons, seminar presentations, publications, notice letters, and regulatory
25 submissions that Fosamax™ had been tested and found to be safe and effective for the
26 treatment and prevention of osteoporosis; and

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1 b. Defendants represented that FosamaxTM was safer than other alternative
2 medications.

3 81. Defendants knew that their representations were false, yet they willfully,
4 wantonly, and recklessly disregarded its obligation to provide truthful representations
5 regarding the safety and risk of FosamaxTM to consumers, including Plaintiff, and the medical
6 community.

7 82. The representations were made by Defendants with the intent that doctors and
8 patients, including Plaintiff, rely upon them.

9 83. Defendants' representations were made with the intent of defrauding and
10 deceiving Plaintiff, other consumers, and the medical community to induce and encourage
11 the sale of FosamaxTM.

12 84. Plaintiff's doctors, and others relied upon the representations.

13 85. Defendants' fraudulent representations evinced its callous, reckless, willful,
14 and depraved indifference to the health, safety and welfare of consumers, including Plaintiff.

15 86. As a direct and proximate result, Plaintiff suffered serious personal injuries.
16 In addition, Plaintiff required and will continue to require healthcare services. Plaintiff has
17 incurred and will continue to incur medical and related expenses. Plaintiff has suffered and
18 will continue to suffer diminished capacity for enjoyment of life, a diminished quality of life,
19 increased risk of premature death, aggravation of preexisting conditions and activation of
20 latent conditions, and other losses and damages. Plaintiff's direct medical losses and cost
21 include care for hospitalization, physician care, monitoring, treatment, medications and
22 supplies. Plaintiff has incurred and will continue to incur mental and physical pain and
23 suffering. Plaintiff has suffered loss of wages and wage-earning capacity.

24 87. Defendants' conduct as described above was committed with knowing,
25 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights
26 and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so

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1 as to punish Defendant and deter it from similar conduct in the future.

2 WHEREFORE, Plaintiff demands judgment against Defendants and seek
3 compensatory damages, and exemplary and punitive damages together with interest, the costs of suit,
4 attorneys' fees and such other and future relief as the Court deems just and proper.

5 **SIXTH CAUSE OF THE ACTION**
6 **(Fraudulent Concealment)**

7 88. Plaintiff restates the allegations set forth above as if fully rewritten herein.

8 89. Defendants made fraudulent misrepresentations with respect to Fosamax™ in
9 the following particulars:

10 a. Defendants represented through its labeling, advertising, marketing
11 materials, detail persons, seminar presentations, publications, notice letters, and regulatory
12 submissions that Fosamax™ was safe and fraudulently withheld and concealed information
13 about the substantial risks of using Fosamax™; and

14 b. Defendants represented that Fosamax™ was safer than other alternative
15 medications and fraudulently concealed information which demonstrated that Fosamax™
16 was not safer than alternatives available on the market.

17 90. Defendants had sole access to material facts concerning the dangers and
18 unreasonable risks of Fosamax™.

19 91. The concealment of information by Defendants about the risks of Fosamax™
20 was intentional, and the representations made by Defendants were known by Defendants to
21 be false.

22 92. The concealment of information and the misrepresentations about Fosamax™
23 were made by Defendants with the intent that doctors and patients including Plaintiff, rely
24 upon them.

25 93. Plaintiff doctors, and others relied upon the representations and were unaware
26 of the substantial dental and oral risks of Fosamax™ which Defendants concealed from

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1 Plaintiff's doctors and Plaintiff.

2 94. As a direct and proximate result of Defendants' fraudulent concealment and
3 misrepresentation, Plaintiff suffered serious personal injuries. In addition, Plaintiff required
4 and will continue to require healthcare services. Plaintiff has incurred and will continue to
5 incur medical and related expenses. Plaintiff has suffered and will continue to suffer
6 diminished capacity for enjoyment of life, a diminished quality of life, increased risk of
7 premature death, aggravation of preexisting conditions and activation of latent conditions,
8 and other losses and damages. Plaintiff' direct medical losses and cost include care for
9 hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff
10 has incurred and will continue to incur mental and physical pain and suffering. Plaintiff has
11 suffered loss of wages and wage-earning capacity.

12 95. Defendants' conduct as described above was committed with knowing,
13 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights
14 and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so
15 as to punish Defendant and deter it from similar conduct in the future.

16 WHEREFORE, Plaintiff demands judgment against Defendants and seek
17 compensatory damages, and exemplary and punitive damages together with interest, the costs of suit,
18 attorneys' fees and such other and future relief as the Court deems just and proper.

19 **SEVENTH CAUSE OF ACTION**

20 **(Equitable Relief)**

21 **(Medical Monitoring Program and Proper Labeling)**

22 96. Plaintiff restate the allegations set forth above as it fully rewritten herein.

23 97. As a direct and proximate result of Defendants' acts, Plaintiff face an increased
24 susceptibility to injuries as described herein. The irreparable threat to their health can only
25 be mitigated by the creation of a medical monitoring fund to provide for a medical
26 monitoring program, including: notifying Plaintiff and subclasses of the defects and the
potential medical harm; funding of a program for the surgical treatment of osteonecrosis of

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1 the jaw; funding a study for the long term effects of Fosamax™ upon Plaintiff; gathering and
2 forwarding to treating physicians information relating to the diagnosis and treatment of
3 injuries which may result from the product; and funding for diagnosis and preventative
4 medical treatment, particularly dental and oral monitoring.

5 98. Plaintiff has no adequate remedy in law in that monetary damages alone do not
6 compensate for the insidious and continuing nature of the harm to them, and only a medical
7 monitoring program which notified Plaintiff and aids in correcting the problems can prevent
8 the greater harms which may not occur immediately and which may be preventable, if proper
9 research is conducted and the health risk are diagnosed and treated before they occur or
10 become worse.

11 99. Plaintiff has suffered irreparable harm as alleged herein and, in the absence of
12 equitable relief, Plaintiff will suffer further irreparable harm such as death and severe and
13 debilitating injuries from continued retention of the defective drug. Without a medical
14 monitoring program, Plaintiff might not receive prompt medical care which could prolong
15 their productive lives, increase prospects for improvement and minimize disability.

16 100. Additionally, Defendants have refused to fully abide by the FDA's request to
17 amend the Fosamax™ product labeling information to warn physicians and patients about
18 the risk of osteonecrosis of the jaw. Because of their failure, prescribing physicians are
19 unable to warn patients to be aware of precursor symptoms which, if properly observed and
20 reported to the physician, could result in discontinuation of Fosamax™ therapy and the
21 prevention or mitigation of serious injury, including osteonecrosis of the jaw. This Court
22 should use its equitable powers, in the interest of the public safety and in order to make sure
23 that prescribing physicians have a complete understanding of the risks associated with
24 Fosamax™ to require Defendant to change its label in a format approvable by the FDA to
25 adequately warn physicians and Fosamax™ patients about the risk of osteonecrosis of the
26 jaw and steps which can be taken to prevent or mitigate its occurrence.

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1 WHEREFORE, Plaintiff demands judgment against Defendants and seek
2 equitable relief in the form of a medical monitoring program this Court's order that Defendants
3 change the labeling of Fosamax™ to appropriately warn of the risk of osteonecrosis of the jaw.

4 **EIGHTH CAUSE OF ACTION**
5 **(Violation of Business & Profession Code Section 17200)**

6 101. Plaintiff restate the allegations set forth above as it fully rewritten herein.

7 102. Plaintiff are informed and believe and allege that Defendants, by the acts and
8 misconduct alleged herein, violated Business and Professions Code sections 17200.

9 103. California Business & Professions Code Section 17200 provides that unfair
10 competition shall mean and include "all unlawful, unfair or fraudulent business practices and
11 unfair, deceptive, untrue or misleading advertising."

12 104. The acts and practices described herein were and are likely to mislead the
13 general public and therefore constitute unfair business practices within the meaning of
14 Business & Professions Code Section 17200. The acts and untrue and misleading advertising
15 set forth in presiding paragraphs are incorporated by reference and are, by definition,
16 violations of Business & Professions Code Section 17200. This conduct includes, but is not
17 limited to:

18 a. Representing to Plaintiff, Plaintiff physicians and the general public
19 that Fosamax™ was safe, fit and effective for human consumption, knowing that said
20 representations were false, and concealing from the Plaintiff, Plaintiff physicians and the
21 general public that Fosamax™ has a serious propensity to cause injuries to users;

22 b. Engaging in advertising programs designed to create the image,
23 impression and belief by consumers, physicians and others that the use of Fosamax™ was
24 safe for human use, had fewer side effects and adverse reactions than other methods for
25 treating mental illness, constituted a convenient, safe form for treating mental illness and
26 would not interfere with daily life, even though the Defendants knew these to be false, and

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1 even though the Defendants had no reasonable grounds to believe them to be true;

2 c. Purposely downplaying and understating the health hazards and risks
3 associated with Fosamax™; and

4 d. Issuing promotional literature deceiving potential users of Fosamax™
5 by relaying positive information and manipulating statistics to suggest widespread
6 acceptability, while downplaying the known adverse and serious health effects and
7 concealing material relevant information regarding the safety of Fosamax™.

8 105. These practices constitute unlawful, unfair and fraudulent business acts or
9 practices, within the meaning of California Business & Professions Code Section 17200, as
10 well as unfair, deceptive, untrue and misleading advertising as prohibited by California
11 Business & Professions Code Section 17500, as set forth herein.

12 106. The unlawful, unfair and fraudulent business practices of Defendants described
13 above present a continuing threat to members of the public in that Defendants continue to
14 engage in the conduct described therein.

15 107. As a result of their conduct described above, Defendants have been unjustly
16 enriched. Specifically, Defendants have been unjustly enriched by receipt of hundreds of
17 millions of dollars in ill-gotten gains from the sale and prescription of Fosamax™ in
18 California, and other states, sold in large part as a result of the acts and omissions described
19 herein.

20 108. Because of the fraudulent misrepresentations made by Defendants as detailed
21 above, and the inherently unfair practice of committing a fraud against the Plaintiff and
22 public by intentionally misrepresenting and concealing material information, the acts of
23 Defendant described herein constitute unfair or fraudulent business practices.

24 109. Plaintiff, pursuant to California Business & Professions Code Section 17203,
25 seek an order of this court compelling the Defendant to provide restitution, and to disgorge
26 the monies collected and profits realized by Defendants, and each of them, as a result of their

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1 unfair business practices.

2 110. Defendants' acts were willful, wanton, reckless and fraudulent; hence, Plaintiff
3 are entitled to exemplary damages, inter alia.

4 WHEREFORE, Plaintiff demands judgment against Defendants and seek
5 compensatory damages, disgorgement, restitution, and exemplary and punitive damages together
6 with interest, the costs of suit, attorneys' fees and such other and future relief as the Court deems just
7 and proper.

8 **NINTH CAUSE OF ACTION**
9 **(Violation of Business & Profession Code Section 17500)**

10 111. Plaintiff restate the allegations set forth above as it fully rewritten herein.

11 112. Plaintiff are informed and believe and thereon allege that Defendants, by the
12 acts and misconduct alleged herein, violated Business & Professions Code Section 17500.

13 113. Plaintiff hereby seek restitution, as well as and punitive damages against
14 Defendants for their violations of section 17500.

15 114. California Business & Professions Code section 17500 provides that it is
16 unlawful for any person, firm, corporation or association to dispose of property or perform
17 services, or to induce the public to enter into any obligation relating thereto, through the use
18 of untrue or misleading statements.

19 115. At all times herein mentioned, Defendants have committed the acts of
20 disseminating untrue and misleading statements as defined by Business & Professions Code
21 Section 17500 by engaging in the following acts and practices with intent to induce members
22 of the public to purchase and use Fosamax™:

23 a. Representing to Plaintiff, Plaintiff physicians and the general public
24 that Fosamax™ was safe, fit and effective for human consumption, knowing that said
25 representations were false, and concealing from the Plaintiff, Plaintiff physicians and the
26 general public that Fosamax™ have a serious propensity to cause injuries to users;

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1 b. Engaging in advertising programs designed to create the image,
2 impression and belief by consumers, physicians and others that the use of Fosamax™ was
3 safe for human use, had fewer side effects and adverse reactions than other methods for
4 treating mental illness, constituted a convenient, safe form for treating mental illness and
5 would not interfere with daily life, even though the Defendants knew these to be false, and
6 even though the Defendants had no reasonable grounds to believe them to be true;

7 c. Purposely downplaying and understating the health hazards and risks
8 associated with Fosamax™; and

9 d. Issuing promotional literature deceiving potential users of Fosamax™
10 by relaying positive information and manipulating statistics to suggest widespread
11 acceptability, while downplaying the known adverse and serious health effects and
12 concealing material relevant information regarding the safety of Fosamax™.

13 116. The foregoing practices constitute false and misleading advertising within the
14 meaning of California Business & Professions Code Section 17500.

15 117. As a result of its false and misleading statements described above, Defendants
16 have been and will be unjustly enriched. Specifically, Defendants have been unjustly
17 enriched by receipt of hundreds of millions of dollars from the sale and prescription of
18 Fosamax™ in California and other states, sold in large part as a result of the false or
19 misleading statements described herein.

20 118. Pursuant to California Business & Professions Code Section 17535, Plaintiff
21 seek an order of this court compelling the Defendants to provide restitution, and to disgorge
22 the monies collected and profits realized by Defendants, and each of them, as a result of their
23 unfair business practices, and injunctive relief calling for Defendants to cease such unfair
24 business practices in the future.

25 **WHEREFORE**, Plaintiff demands judgment against Defendants and seek
26 compensatory damages, disgorgement, restitution, and exemplary and punitive damages together

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1 with interest, the costs of suit, attorneys' fees and such other and future relief as the Court deems just
 2 and proper.

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5 **TENTH CAUSE OF ACTION**
 6 **(Loss of Consortium)**

7 119. Plaintiff restate the allegations set forth above as if fully rewritten herein.

8 120. Plaintiff Ruth P. Morris and Buddy W. Penn bring this cause of action.

9 121. By reason of the injuries sustained by Plaintiff Anne e. Clayton, Plaintiff Ruth A.
 10 Morris has been and will continue to be deprived of consortium, society, comfort, protection, and
 11 service, thereby causing and continuing to cause said Plaintiff grief, sorrow, mental anguish,
 12 emotional distress and pain and suffering.

13 122. By reason of the injuries sustained by Plaintiff Judy C. Penn, Plaintiff Buddy W. Penn
 14 has been and will continue to be deprived of consortium, society, comfort, protection, and service,
 15 thereby causing and continuing to cause said Plaintiff grief, sorrow, mental anguish, emotional
 16 distress and pain and suffering.

17 **WHEREFORE,** Plaintiff demands judgment against Defendants and seek
 18 compensatory damages, and exemplary and punitive damages together with interest, the costs of suit,
 19 attorneys' fees and such other and future relief as the Court deems just and proper.

20 **ELEVENTH CAUSE OF ACTION**
 21 **(Punitive Damages)**

22 123. Plaintiff restate the allegations set forth above as if fully rewritten herein.

23 124. Defendants have repeatedly engaged in a pattern of conduct of deliberately
 24 avoiding FDA recommendations as to public hazards which should be warned about.

25 125. For instance, in March, 2000, Merck completed a study called VIGOR (Vioxx
 26 Gastrointestinal Outcomes Research) relating to its prescription Cox-2 inhibitor, Vioxx. The
 VIGOR study showed that Vioxx patients had more than double the rate of serious

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1 cardiovascular problems than those on Naproxen, an older non-steroidal anti-inflammatory
2 drug. The study was published in the New England Journal of Medicine.

3 126. In September, 2001, the FDA warned Merck to stop misleading doctors about
4 Vioxx's effect on the cardiovascular system. Merck was admonished to stop minimizing the
5 risks of the drug in its marketing. Despite that, Merck refused to adequately warn physicians
6 and patients about the risk of heart attacks and Vioxx.

7 127. On August 25, 2004, a representative from the FDA presented results of a
8 database analysis of 1.4 million patients. The analysis demonstrated that Vioxx users were
9 more likely to suffer a heart attack or sudden cardiac death than those taking Celebrex or
10 older non-steroidal drugs. The FDA representative concluded that Vioxx was linked to more
11 than 27,000 heart attacks or sudden cardiac deaths nationwide from the time it came on the
12 market in 1999 through 2003.

13 128. On August 26, 2004, Merck released a press statement which refuted the FDA
14 analysis and restated Merck's support for the cardiovascular safety of Vioxx.

15 129. On September 30, 2004, Merck recalled Vioxx from the market, after having
16 to halt the APPROVe (Adenomatous Polyp Prevention On Vioxx) study. The study was
17 underway to evaluate the use of Vioxx for recurrent colon polyps. The researchers found an
18 alarming number of cardiovascular events among the drug's users in the APPROVe study.

19 130. At that same time, Defendants were aware that the FDA, as of August 24,
20 2004, was advising Merck to warn about the risk of osteonecrosis of the jaw for its
21 FosamaxTM patients. Because Merck knew that its blockbuster drug Vioxx was about to be
22 pulled from the market, placing more importance on the more than \$3 billion annual sales
23 of FosamaxTM, Merck deliberately chose not to amend its packaging of FosamaxTM to include
24 the risk of osteonecrosis of the jaw, fearing that such a warning would result in reduced
25 revenues for its second largest income producer, FosamaxTM.

26 131. Merck's acts were willful and malicious in that Merck's conduct was carried

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1 on with a conscious disregard for the safety and rights of Plaintiff and all others taking
2 Fosamax™. Merck's unconscionable conduct thereby warrants an assessment of exemplary
3 and punitive damages against Merck in an amount appropriate to punish Merck and deter
4 similar conduct in the future.

5 WHEREFORE, Plaintiff demands judgment against Defendants and seek
6 compensatory damages, and exemplary and punitive damages together with interest, the costs of suit,
7 attorneys' fees and such other and future relief as the Court deems just and proper.

8 **PRAYER FOR RELIEF**

9 WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and/or
10 severally, as follows:

- 11 a. For general damages in an amount to be proven at the time of trial;
- 12 b. For special damages in an amount to be proven at time of trial;
- 13 c. For exemplary and punitive damages in an amount to be proven at the time of
14 trial, and sufficient to punish Defendant or to deter Defendant and others from repeating the
15 injurious conduct alleged herein;
- 16 d. For prejudgment and post-judgment interest on the above general and special
17 damages;
- 18 e. For disgorgement;
- 19 f. For restitution;
- 20 g. For costs and attorneys' fees; and
- 21 h. All other relief that Plaintiff may be entitled to at equity or at law, including
22 but not limited to the funding of a medical monitoring program and compelling Defendants
23 to adequately warn about the risk of osteonecrosis of the jaw with use of Fosamax™.

24 **DEMAND FOR JURY TRIAL**

25 Plaintiff demands a trial by jury on all claims so triable in this action.

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5 Dated: August 15, 2006

Respectfully submitted,

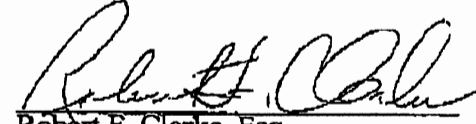
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PHILLIPS & ASSOCIATES

7

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By



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